VIA ECF

The Honorable Rukhsanah L. Singh, U.S.M.J. United States District Court District of New Jersey Clarkson S. Fisher Fed. Bldg. & U.S. Courthouse 402 East State Street Trenton, New Jersey 08608

Re: In re: Insulin Pricing Litigation

No. 2:23-md-03080-BRM-RLS

MDL No. 3080

ESI Protocol Disputes

Dear Judge Singh:

Pursuant to the Court's instructions at the March 12, 2024 Case Management Conference and Local Civil Rules 16.1 and 37.1, Defendants submit this letter in the above-captioned matter because the parties have reached an impasse as to certain provisions in the ESI Protocol.

Defendants respectfully request the Court's guidance in resolving these disputes.

I. Background

The parties have actively attempted to resolve these disputes for several months. The parties first exchanged proposed drafts of the ESI Protocol in November 2023. The parties have met-and-conferred four times since then and exchanged several drafts to try to reach agreement. On February 15, the parties held a final meet-and-confer, but reached an impasse and agreed to bring the remaining disputes to Your Honor. On March 1, 2024, Plaintiffs provided a list of provisions for which the parties are at an impasse. While the parties have successfully resolved many disagreements through this process, they remain at an impasse as to the following items:

1. Whether the obligations in this ESI Protocol should apply to all Plaintiffs and Defendants in this MDL, as has been the case in all prior ESI Protocols, *see infra* p. 5;

- 2. Whether the definition of a "document family" should be broadened to include hyperlinked files, requiring producing parties to always identify and collect such files individually regardless of whether it is technologically feasible to do so, *see infra* p. 7;
- 3. Whether a producing party must allow the opposing party to dictate the terms of its document search, review, and production, and provide "discovery on discovery" without evidence of any deficiency or concern in its document-production process, *see infra* p. 9 including:
 - a) Whether a producing party is prohibited from using commercially available email threading tools, *see infra* p. 11;
 - b) Whether a producing party is prohibited from using both search terms and technology assisted review ("TAR") to identify and review for responsive documents, *see infra* p. 14;
 - c) Whether a producing party is prohibited from: (1) redacting (a) personal identifying information ("PII"), (b) identifying information about non-diabetes products not at issue in this litigation, or (c) members of Pharmacy & Therapeutics Committees ("P&T Committees") other than Pharmacy Benefit Manager ("PBM") employees; or (2) slipsheeting fully non-responsive attachments, *see infra* p. 17;
 - d) Whether a producing party must incur the cost of producing documents in native format and full color as a matter of course, *see infra* p. 21; and
- 4. Whether all references to "responsive" materials in the ESI Protocol should be changed to "relevant," *see infra* p. 22.

II. Argument

The parties' disputes over the ESI Protocol stem from a simple theme: Plaintiffs want to reinvent the wheel and then dodge any obligations that result from doing so. Counsel for two-thirds of the Plaintiff tracks and all the Defendants have successfully negotiated ESI Protocols in earlier insulin pricing cases. Nearly a million documents were produced, and then re-produced several times across cases, pursuant to those ESI Protocols. Multiple cases have made it all the way through discovery, and not once did a single party raise any issue with the sufficiency or format of productions pursuant to the ESI protocols in those cases. Despite this, Plaintiffs now insist on starting from scratch with materially different provisions. As Exhibit B shows, Plaintiffs' proposal contains nearly 100 additions to and 70 deletions from Defendants' proposal (which largely mirrors protocols previously agreed to in other insulin pricing cases). For example, Plaintiffs want to expand the definition of document families; contract the scope of permissible redactions and slipsheets; unilaterally dictate Defendants' collection, review, and

¹ As this Court is aware, this MDL was formed in 2023, nearly six years after the first insulin pricing case was filed in 2017. Immediately after that first case, three others were filed in quick succession. Several years later, several Attorneys General followed suit before the MDL was formed. Prior to the MDL formation, the various Courts entered stipulated ESI Protocols in six cases, all of which are either part of or coordinated with the MDL. This includes *In re Insulin Pricing Litigation*, Case No. 17-669 (DNJ); *MSP Recovery Claims Series, LLC v. Aventis U.S. LLC, et al.*, Case No. 18-2211 (DNJ); *Minnesota v. Sanofi-Aventis U.S. LLC, et al.*, Case No. 18-14999 (DNJ); and *In re Direct Purchaser Insulin Pricing Litigation*, Case No. 20-03426 (DNJ) (collectively, "the New Jersey Actions"); as well as *Mississippi v. Eli Lilly & Co., et al.*, Case No. 21-674 (S.D. Miss.); *Arkansas v. Eli Lilly & Co., et al.*, Case No. 22-549 (E.D. Ark.), and *Kansas v. Eli Lilly & Co.*, et al., Case No. 23-4002 (D. Kan.).

² To highlight the consistency between Defendants' current proposal and the ESI Protocols in prior insulin pricing cases, Defendants have enclosed Exhibit D, which is a chart comparing the language of Plaintiffs' proposal, Defendants' proposal, and the ESI Protocol previously entered in *Mississippi v. Eli Lilly & Co., et al.*, Case No. 21-674 (S.D. Miss.). For the Court's convenience, the complete *Mississippi* ESI Protocol is enclosed as Exhibit E.

production processes; and even abandon something as common and accepted as email threading. Yet, Plaintiffs fail to provide a valid reason for many of their proposed changes or for deviating from the language included in virtually every prior ESI protocol involving the same parties and same issues.

Plaintiffs now seek not only to add substantial and burdensome requirements to the production of ESI, but also to excuse themselves from complying with those same requirements. See Ex. A, Row 1. This MDL was formed to create an efficient, fair, and comprehensive framework for the insulin pricing matters, and was sent to the District of New Jersey in part because of the work already done here. This Court has recognized the importance of "not reinventing the wheel" on discovery work in this MDL. See Sept. 12, 2023 Hearing Tr. at 24. Plaintiffs' plan to redraft the ESI Protocol from scratch—with extensive new requirements and restrictions—and then make those obligations entirely one-sided undermines the MDL's efficiency and universality.

Despite the inefficiency of renegotiating the ESI Protocol terms, Defendants have attempted to find common ground, and integrated many of Plaintiffs' newly-proposed provisions, even when they were more onerous or restrictive than standard e-discovery practice.³ But Plaintiffs' other proposals discussed herein are a clear overreach: they are one-sided, unsupported by standard e-discovery practice, technology or case law, and would impose a disproportionate burden⁴ on the producing parties (where, if prior cases are any guide,

³ For example, Defendants agreed to Plaintiffs' language on 'deleted files notification' under preservation obligations in Section III.A. of the ESI Protocol.

⁴ Defendants have set out their position without providing formal declarations regarding the burden attendant to Plaintiffs' proposed order. If the Court is inclined to adopt Plaintiffs'

Defendants are likely to be the parties producing the largest quantities of documents).

Defendants request that the Court enter their proposed ESI Protocol, attached as Exhibit C.⁵

A. The ESI Protocol should apply to all parties, not just to Defendants or select Plaintiffs who are a part of this MDL.

Plaintiffs have added language that would limit the applicability of the ESI Protocol—including all of the new onerous provisions discussed herein—*only to Defendants*. *See* Ex. A, Rows 1, 14. In initial negotiations, Plaintiffs proposed that the ESI Protocol should absolve them of the obligation to engage in discovery at all—an obvious nonstarter. But their current proposal still presents virtually the same problem by providing that Plaintiffs' ESI obligations will be governed not by this ESI Protocol, but by some future, indeterminate protocol. And Plaintiffs go a step further and attempt to dictate—without saying so—the structure of the MDL, insisting that the only Plaintiffs that will participate in discovery are named class plaintiff representatives and bellwether plaintiffs, despite the fact that there have been no meaningful

proposal on any of the disputed issues, Defendants request the opportunity to fully brief those issues and submit accompanying declarations.

⁵ As described above, there are over 150 changes (additions or subtractions) still in dispute between the parties' competing versions. Out of respect for the Court's time, Defendants have not included every disputed difference in this briefing. Per the Court's direction, Defendants have also included as "Exhibit A" a quick-reference chart listing Plaintiffs' and Defendants' key disputed provisions.

⁶ "**Applicability to Plaintiffs.** The obligations imposed on the Parties pursuant to this ESI Order, other than the preservation obligations set forth in Paragraph B, will not become operative on any individual named Plaintiff until the action in which it is named is selected as a bellwether action, or on any class Plaintiff until that Plaintiff files a class action on behalf of a proposed class and/or is subsequently designated by counsel as an additional or alternative proposed class representative, or upon agreement between the individual named Plaintiff or class Plaintiff and the Defendants, or upon further order of the Court." Plaintiffs' Nov. 7, 2023 Draft ESI Protocol.

discussions, either between the parties or with the Court, about the propriety of bellwethers in this MDL.⁷ See Ex. A, Rows 1, 14.

Sophisticated Plaintiffs like the attorneys general, localities, and union health plans who bring these actions cannot impose highly-specific, burdensome requirements on Defendants while exempting themselves from those same requirements. *See, e.g., Sentis Grp., Inc. v. Shell Oil Co.*, 763 F.3d 919, 925 (8th Cir. 2014) ("Litigation in general and discovery in particular . . . are not one sided."). By contrast, Defendants' proposed ESI Protocol allows the parties to meetand-confer when a party's specific needs may require variation from the ESI Protocol, *without* imposing one-sided discovery obligations. *See* Ex. A, Row 1. This approach allows discovery to proceed fairly and uniformly, while preserving flexibility when required. This more standard bilateral discovery approach will also act as an important check, disincentivizing parties from making unreasonable, one-sided demands.

Finally, Plaintiffs not only attempt to reinvent the wheel with their proposed ESI Protocol in the MDL, but they also seek to impose these new burdens on four prior cases: Plaintiffs' proposed definition of "Litigation" in the MDL ESI Protocol would "expressly include[]" the four New Jersey actions. *See* Ex. A, Row 3. This is an improper attempt to override the terms of the ESI Protocols entered in those cases and to unwind the significant work that has already been done there under the terms of the relevant ESI Protocols. Plaintiffs have no good explanation for requiring this, and doing so would only encourage disputes where none have been had. The

⁷ For avoidance of doubt, Defendants disagree with Plaintiffs on whether bellwethers are necessary in this MDL. Defendants do not include an extended argument here because ultimately, a dispute over bellwethers goes to overarching MDL management and structure. A dispute over bellwethers is not suited for an ESI Protocol, which is intended to govern the more technical aspects of electronic discovery and document production.

Court should reject this attempt to impose additional post-hoc obligations in those cases, particularly when significant discovery has already been done in most of those cases.

B. Plaintiffs overreach by attempting to expand the definition of "document family" to include hyperlinked files when courts have recognized both that hyperlinked files are distinct from attachments and that collecting them is disproportionately burdensome.

Plaintiffs insist that Defendants treat and produce "hyperlinks" as so-called "modern attachments" (by defining them as part of a "document family" in Plaintiffs' proposed Section II, and requiring all family members to be produced in Section VII). *See* Ex. A, Rows 2, 12. The problem with Plaintiffs' proposal is simple: hyperlinks are *not* attachments. *Nichols v. Noom Inc.*, 2021 WL 948646, at *4 (S.D.N.Y. March 11, 2021) ("To start, the Court does not agree that a hyperlinked document is an attachment. While the Court appreciates that hyperlinked internal documents could be akin to attachments, this is not necessarily so."); *In re Meta Pixel Healthcare Litig.*, 2023 WL 4361131, at *1 (N.D. Cal. June 2, 2023) ("[T]he ESI protocol should make clear that hyperlinked documents are not treated as conventional attachments for purposes of preserving a 'family' relationship in production."). ESI Protocols in prior insulin pricing cases did not include hyperlinks in the definition of document families. Forcing Defendants here to change course and treat hyperlinks as attachments in collection, processing, review, or production would impose an unreasonable and disproportionate burden on all Defendants by raising significant technical difficulties and generating unnecessary costs.

There is a meaningful technical difference between hyperlinks and attachments.

Attachments are static components of a .msg email file and are maintained together as such in the ordinary course. This means that from collection through processing for review, they are

automatically linked to each other and can be easily collected, reviewed, and produced together.

Hyperlinks, on the other hand, are not part of the .msg email file in which they are transmitted, are not static, and are not automatically associated with the email or document through which they are transmitted in the ordinary course. Rather, hyperlinks are connections that point a message recipient to a separate specific document's location, *as it exists at that time*, much more akin to a website link than an attachment. The hyperlink therefore operates only as a *reference* to a separate document—not as an *attachment*.

Because hyperlinks are not attachments, collecting, processing, reviewing, or producing them as "family" members with the documents in which they are transmitted presents unique challenges. *First*, it may not be technologically feasible to identify, collect, and produce hyperlinked documents—particularly given Plaintiffs' position that the relevant discovery period stretches back at least to 2011. *See Meta*, 2023 WL 4361131, at *1 (rejecting argument that hyperlinks are part of document family due, in part, to lack of "commercially available methods" to "automatically collect[] links to non-public documents"). *Second*, as courts have recognized, even if possible, collecting hyperlinks is unduly burdensome and costly, often requiring manual searching to try to connect a document containing a hyperlink to the linked document. *See Nichols*, 2021 WL 948646, at *4–5; *accord Porter v. Equinox Holdings*, 2022 WL 887242, at *2 (Cal. Sup. Ct. 2022) (rejecting argument that hyperlinks are attachments, explaining that

⁸ The mere fact that one document is referenced within another document does not mean the two are attached. This letter, for example, cites dozens of other documents, including cases, rules, the Sedona Principles, and orders entered in other cases. But the mere fact that this letter *references* another document—whether by use of hyperlinks or other identifying information, such as case reporter citations—is not the same as these materials being *attached* to this letter. By contrast, the exhibits to this letter can properly be considered attachments. Not only are they referenced in this letter, but copies thereof have been provided alongside this letter as part of a single submission. As a result, the exhibits are not only referenced in but also will be located with this letter—unlike other materials cited herein that have not been attached.

hyperlinks "present unique challenges that make them different from email attachments"). Finally, due to the dynamic nature of the linked files, there is no guarantee that any given file that is identified, collected, and associated to a prior, responsive document is now exactly the same as it was at that time, much less responsive.

Yet, Plaintiffs are now attempting to require that all Defendants undertake that manual, burdensome process for all collected documents, on a mere hunch that some hyperlink in some email from any time period may contain material that is not available through other means. That type of overreach is not proportional to the needs of this case. Rather, these provisions—as with many others in dispute—stem from Plaintiffs' misguided belief that they are entitled to every document potentially related to this case, irrespective of cost, burden, or whether the document itself is responsive to discovery requests. The Federal Rules, and federal courts, squarely reject that position. *See* Fed. R. Civ. P. 26(b) (discovery must be "relevant" *and* "proportional to the needs of the case"); *In re Diisocyanates Antitrust Litig.*, 2021 WL 4295729, at *6 (W.D. Pa. Aug. 23, 2021) (the principles of reasonableness and proportionality "do[] not require perfection"); The Sedona Conference, TAR Case Law Primer, Second Ed., 24 Sedona Conf. J. 1, 32 (2023) ("reasonableness, rather than perfection, is the standard in discovery") (collecting cases). This Court should do the same.

C. Plaintiffs' attempt to unilaterally dictate all of Defendants' collection, review, and production processes is contrary to case law, industry standards, and agreements in prior insulin pricing matters.

Courts within the Third Circuit consistently recognize that the producing party is in "the best position" to decide how to preserve, collect, review, and produce its own documents, and leave such decisions to "the producing party's sound discretion." *See Ford Motor Co. v. Edgewood Properties, Inc.*, 257 F.R.D. 418, 427 (D.N.J. 2009); *see also MSP Recovery Claims*,

Series, LLC v. Sanofi-Aventis U.S. LLC, 2022 WL 20359241, at *13 (D.N.J. Feb. 8, 2022) (producing party is "in the best position to determine the procedures, methodologies, and technologies appropriate for producing their own ESI"). And while a requesting party may prefer other methods, it may not impose its preferred method or force a producing party to change its approach. See Livingston v. City of Chicago, 2020 WL 5253848, at *3 (N.D. Ill. Sept. 3, 2020) ("Plaintiffs' insistence that [the producing party] must collaborate with them to establish a review protocol and validation process has no foothold in the federal rules governing discovery.").

Consistent with those principles, "discovery on discovery" is the exception, not the rule. A receiving party may take discovery on the producing party's discovery process only if it identifies a "specific deficiency" in the producing party's production. The Sedona Principles, Third Ed.: Best Practices, Recommendations & Principles for Addressing Electronic Document Production, 19 Sedona Conf. J. 1 (2018) at 118 ("[A] responding party is best situated to preserve, search, and produce its own ESI. [This Principle] is grounded in reason, common sense, procedural rules, and common law, and is premised on each party fulfilling its discovery obligations without direction from the court or opposing counsel, and eschewing 'discovery on discovery,' unless a specific deficiency is shown in a party's production."); *see also Fish v. Air & Liquid Sys. Corp.*, 2017 WL 697663, at *6 (D. Md. Feb. 21, 2017) (finding that discovery on discovery "is not an appropriate topic of discovery and numerous courts have disallowed such discovery.").

Notwithstanding those settled principles, Plaintiffs now seek "discovery on discovery" at the outset, by mandating the provision of detailed information about—and the ability for Plaintiffs to second-guess and weigh in on—the "precision" and "validation" of a producing

party's discovery process. *See* Ex. A, Rows 5, 6. And rather than streamlining discovery in this MDL by using the time-tested provisions from prior ESI protocols, Plaintiffs seek to dictate rigid and burdensome new requirements on Defendants' collection, review, and production processes by prohibiting industry standard eDiscovery practices such as email threading or the combined use of search terms and TAR, and requiring native and full-color production format. *See* Ex. A, Rows 7, 9, 10, 11. They seek to impose these mandates while simultaneously requiring Defendants to provide detailed information to "increase the relative precision or proportion of relevant or responsive ESI," as well as detailed information about Defendants' databases. *See* Ex. A, Rows 6, 7, 9, 13. Plaintiffs even seek to impose these requirements on irrelevant information to which they are not entitled by limiting Defendants' ability to redact irrelevant, sensitive information about products not at issue in this case, which has been routinely redacted in all prior insulin pricing cases. *See* Ex. A, Row 11.

1. <u>Email Threading</u>

Plaintiffs want this Court to prohibit the use of email threading. *See* Ex. A, Row 9. But federal courts routinely allow email threading, and for good reason: it can create a streamlined and accurate review process for all parties and significantly reduce eDiscovery costs. *See Malone v. U.P.S., Inc.*, 2022 WL 18775906, at *2 n.2 (E.D. Pa. Nov. 28, 2022) (in certain circumstances "[t]hreading prevents the review team from reviewing information multiple times and reduces the likelihood of coding mistakes."). Threading has been permitted in every prior

⁹ See also ACLU Foundation of S. Cal. v. U.S. Immigration & Customs Enforcement, 2023 WL 8539484, at *11 (C.D. Cal. Dec. 8, 2023) (ordering use of "email threading and deduplication of records prior to processing to reduce the number of records to be processed and produced"); Sierra Club v. EPA, 2018 WL 10419238, at *5 (N.D. Cal. Dec. 26, 2018) (explaining how "the standard technique of 'threading' emails to reduce duplicate content in emails chains . . . reduces the time and complexity of reviewing emails"); Jacobson Warehouse

insulin pricing ESI Protocol and is a commonly used tool for reducing the burdens of producing duplicative emails. *See* David Cohen, Erica Strauss, & Beth Wurzel, *Introduction—Practical issues in electronic discovery*, eDiscovery for Corporate Counsel § 13:2 (2023) ("It is typical today to de-duplicate and filter data prior to review by attorneys."). Indeed, threading is accepted to such an extent that some federal district courts have made it the default in their model ESI Orders.¹⁰

Permitting parties to use email threading to remove duplicative information from review and production not only satisfies Rule 26(b)(1), but also strikes the appropriate balance between a requesting party's need for relevant information and the burdens imposed by duplicative discovery on *both* parties, as it reduces both a producing and a requesting party's need to review duplicative email threads. *See* Fed. R. Civ. Prod. 26(b)(2)(B)–(C) (limiting discovery of ESI if "unreasonably cumulative or duplicative, or [when it] can be obtained from some other source that is more convenient, less burdensome, or less expensive"). Further, Defendants' proposal includes a failsafe option for requesting any needed lesser included emails by permitting requests on a case-by-case basis and presumptively granting reasonable requests. This would resolve any issues where, for instance, a party wanted a standalone version of a certain portion of an email chain as a trial exhibit.

Co., Inc. v. Schnuck Markets, Inc., 2020 WL 853736, at *6 (E.D. Mo. Feb. 20, 2020) (finding email threading to be an "indispensable component of producing a fair and accurate copy of a document or other 'material.'"), aff'd, 13 F.4th 659 (8th Cir. 2021); United States v. Heine, 2017 WL 1393493, at *10 (D. Or. April 11, 2017) (ordering the ESI vendor to "identify and eliminate 'near duplicates' and employ 'email threading'" as part of the production process) (citing The Electronic Discovery Institute, The Federal Judges' Guide to Discovery 1, 74–75 (2015)).

¹⁰ See, e.g., W.D. Wash., Model ESI Agreement, https://www.wawd.uscourts.gov/sites/wawd/files/ModelESIAgreement CLEAN 2.1.23.pdf (last visited Feb. 8, 2024).

Threading typically reduces document volume by 10-30%, so the potential impact here is significant. Prohibiting threading would significantly increase the cost and burden of discovery, requiring the review of hundreds of thousands of additional pages of cumulative and duplicative content by *both* parties, as well as raising the hosting fees that those additional records would cause. It would also impose needless burdens during the redaction process, as a producing party would be required to separately, manually redact the *same* information in multiple copies of the *same* email thread.

While Plaintiffs offered to allow Defendants to thread for review, but not for production, that is a hollow "compromise." See Ex. A, Row 9. It is based on the incorrect assumption that Defendants easily can, and would, propagate the coding from the most inclusive email thread down to other versions of emails in that same thread. But Defendants cannot easily do that, nor would it be responsible for them to do so here. First, standard document review platforms like Relativity do not have an automated process that would allow the bulk copying of coding from one email to all other emails in its thread across an entire production set. Rather, that would require an extensive manual effort accounting for threads or thread groups that may have mixed coding for responsiveness, privilege, and/or confidentiality, or may require different redactions. Any efficiencies gained from threading could easily be lost in that manual process. Second, in many circumstances, manually propagating coding will not be a straight line from the mostinclusive email to the original email in the thread. Email threads are complex and can extend in different directions where the participants, content, and subject-matter change, and introducing a manual process for propagating coding is not only likely to introduce unnecessary complexities, but it is also inefficient. No automatic decisions can responsibly be made about the responsiveness, privilege, or confidentiality coding of any one email based on that of another

email in the same thread. Plaintiffs' "compromise" is no compromise at all, and Plaintiffs offer no persuasive reason for rejecting threading, much less any reason why the parties should change course on a process permitted in all prior insulin pricing cases.

2. <u>Search Terms and TAR</u>

Plaintiffs also seek to prohibit Defendants from using another common and effective method for culling large volumes of data: the use of search terms in conjunction with technology-assisted review ("TAR"). See Ex. A, Rows 6, 7. Defendants' proposed language, which would allow parties to use both search terms and TAR in identifying potentially responsive documents, is more than sufficient to ensure that each party's approach to discovery is reasonable and proportional to the needs of the case, while respecting that each producing party is best situated to determine its specific methods. For example, Defendants' proposed language requires that if search terms are used, the parties will confer over data sources and search terms *prior* to the producing party's review. See Ex. A, Row 6. And if a party elects to use TAR to cull potentially responsive ESI—that is, if it plans to use TAR to identify documents that will be withheld as non-responsive—it must disclose this before implementing TAR, so that the parties can meet and confer as to any concerns over how TAR will be applied. See Ex. A. Row 7. This proposal achieves reasonable transparency but still appropriately allows each producing party to use collection, search, review, and validation methods that are reasonable in light of its specific circumstances. Affording each producing party the discretion to determine whether to use search terms or TAR or both over a potential review population is the standard and accepted approach, and has been permitted in prior ESI protocols in the insulin pricing cases.

Plaintiffs' proposed language, by contrast, inappropriately shifts control of Defendants' culling, review, and production processes into Plaintiffs' hands. Plaintiffs' position is that

Defendants cannot first use relevant search terms to narrow the document population on which TAR is applied. That is contrary to the opinions of most courts that have confronted this issue and upheld using search terms in conjunction with TAR to identify responsive documents. See, e.g., In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig., 337 F.R.D. 610, 616 (D.N.J. 2020) ("Ample case law exists to support [the] position that in appropriate instances layering [of search terms and TAR] may be done."); In re Diisocyanates, 2021 WL 4295729 (recognizing the propriety of using search terms to cull in addition to applying TAR); In re Biomet, 2013 WL 1729682 (N.D. Ind. Apr. 18, 2013) (finding that the benefit of requiring TAR alone without first utilizing search terms to cull population did not outweigh burden, and upholding defendant's use of search terms to cull collected documents from 19.5 million to 3.9 million before applying TAR)¹²; The Sedona Conference, TAR Case Law Primer, Second Ed., 24 Sedona Conf. J. 1, 51–53 (2023) (noting that courts within the Third Circuit allow combined use of search terms and TAR).

The mountain of case law supporting using search terms to cull the universe of records before TAR reflects the real burdens associated with using TAR without search terms. If

¹¹ Plaintiffs' proposal also ignores that recent advances in TAR, specifically active learning tools, can be used to identify and *prioritize* the review and potential production of more relevant documents in a review population (to the benefit of both parties), even where it is *not* used to exclude any records from review or production. But Plaintiffs would still prohibit a party's combination of search terms and TAR if that party uses TAR for *any* purpose (including internal fact investigation or review prioritization), and *even if* Defendants' use of TAR in no way impacts the documents that Plaintiffs receive. *See* Ex. A, Row 7.

¹² See also Livingston, 2020 WL 5253848, at *3; Huntsman v. Sw. Airlines Co., 2021 WL 3504154, at *3 (N.D. Cal. Aug. 10, 2021); Bridgestone Ams., Inc. v. Int'l Bus. Machs. Corp., 2014 WL 4923014, at *1 (M.D. Tenn. July 22, 2014); United States ex rel. Proctor v. Safeway, Inc., 2018 WL 1210965, at *3 (C.D. Ill. Mar. 8, 2018); In re Valsartan, 337 F.R.D. at 616; Maurer v. Sysco Albany, LLC, 2021 WL 2154144, at *8 (N.D.N.Y. May 27, 2021); In re Diisocyanates, 2021 WL 4295729, at *12–13; Klein v. Facebook, Inc., 2021 U.S. Dist. LEXIS 175738, at *8–9 (N.D. Cal. Sept. 15, 2021).

Plaintiffs get their way, Defendants would need to host swaths of irrelevant data that could have been filtered out through appropriate search terms. In a case of this magnitude, those hosting costs alone could be substantial for each Defendant. And this limitation would make the use of TAR itself more expensive, as any analytics would have to be run across a significantly larger number of records.

Consistent with that body of precedent, the Sedona Principles, this Court's prior approach, and the practical burdens associated with prohibiting search terms on top of TAR, each producing party must be able to choose its own review culling methods so that discovery can proceed in the most efficient and proportional manner.

3. Plaintiffs' Intrusion on Defendants' Search Processes

Not content with limiting or prohibiting the industry standard discovery tools that

Defendants may use and have access to, Plaintiffs also demand that they be allowed to
micromanage Defendants' review processes. For example, Plaintiffs insist that Defendants
provide them with unspecified statistical information and the ability to second-guess the
"precision" and "validation" of a producing party's discovery process, regardless of the review
method used, as well as detailed information about inaccessible data sources and search terms
(including hit reports). See Ex. A, Rows 4, 5, 6. But these demands—none of which were
present in any of the ESI protocols in the prior insulin pricing cases—run afoul of the principle
"eschewing 'discovery on discovery." See The Sedona Principles, Third Ed., 19 Sedona Conf.
J. at 118. They are unnecessary given the numerous meet-and-confer obligations already in the
ESI Protocol and the proven success of the ESI Protocol provisions proposed by Defendants.

Indeed, Defendants' proposal *already* requires the parties to meet and confer about the development of search terms and any related concerns. *See* Ex. A, Row 6. Ultimately,

Plaintiffs' prescriptive approach fails to provide the necessary flexibility in a producing party's review and collection processes, and the Court should reject Plaintiffs' attempts to inappropriately intervene in decisions better left to the producing party.

4. Permissible Redactions and Slipsheets

Plaintiffs also seek access to documents and information to which they are not entitled. See Ex. A, Row 11, 12. "[A] party [] is not entitled to receive every piece of irrelevant information in responsive documents if the producing party has a persuasive reason for why such information should be withheld." See In re Takata Airbag Products Liability Litigation, 2016 WL 1460143, at *2 (S.D. Fla. Mar. 1, 2016) (permitting relevance redactions); see also Krishanthi v. Rajaratnam, 2023 WL 5605565, at *8 (D.N.J. Aug. 30, 2023) (permitting redactions after "consider[ing] the rule of proportionality, which guards against redundant or disproportionate discovery"). Following this principle, every ESI Protocol entered in the prior insulin pricing cases—including cases now in the MDL, and the New Jersey Actions—has permitted specific, narrowly-defined, and negotiated redactions for *non*-diabetes medications that do not relate to any claim or defense in this MDL, as well as for PII. Those protocols also permitted a producing party to produce slipsheets in place of entirely non-responsive attachments. Plaintiffs now seek to upend the parties' prior agreements and demand that Defendants produce highly-sensitive, competitive information about non-diabetes products that are not at issue in this MDL, sensitive PII, members of P&T Committees other than PBM employees, as well as wholly non-responsive attachments (meaning that *nothing* in the document is responsive to a document request). The Court should reject this change.

Plaintiffs' complaints make clear that the scope of their allegations are limited to a purported "Insulin Pricing Scheme." Information regarding non-diabetes medications is highly

confidential and commercially sensitive for Defendants. Defendants' concerns with protecting such sensitive information takes on heightened importance here because productions may be used across all cases in the MDL, and because the various Defendants compete and negotiate with each other—and with many of the Plaintiffs themselves—in the markets for PBM services and non-diabetes medications. Plaintiffs' proposed approach would result in unnecessary disclosure of this information, even though non-diabetes medications are not at issue in the MDL. Rule 26(b)(1)'s "fundamental principles" of relevance and proportionality demand that Defendants be afforded the ability to redact *irrelevant*, and potentially competitively damaging, information based on the "careful and realistic assessment of [Plaintiffs'] actual need" to prove their claims or defenses in the MDL. *See* 2015 Year-End Report on the Federal Judiciary at 7 (Dec. 31, 2015) (Roberts, C.J.); *Takata Airbag Products*, 2016 WL 1460143, at *2 (granting defendant's request to redact certain irrelevant, competitively sensitive information in MDL involving competitors where "disclosing such information could provide its competitors with competitively sensitive information to the ultimate detriment of each [d]efendant").

In the same vein, Defendants should be permitted to slipsheet wholly non-responsive documents that are merely included for family-completeness. *See* Ex. A, Row 12. This would not only allow Defendants to protect commercially sensitive and completely irrelevant material from disclosure, but would also reduce the burden on the producing party by limiting the number of (irrelevant) documents that a producing party needs to review for issues like privilege and reductions. Plaintiffs would suffer no prejudice, as Defendants' proposal already allows a requesting party that believes a non-responsive slipsheet is relevant to "request production of *any* attachment withheld solely on the ground of non-responsiveness." *See* Ex. A, Row 12.

Plaintiffs' approach to PII would similarly result in the production and potential disclosure of highly sensitive, personally identifying information despite its irrelevance to Plaintiffs. The limited PII redactions proposed by Defendants are appropriate here, as recognized under prior ESI protocols and in this Court. *See Columbus Life Ins. Co. v. Wilmington Tr., N.A.*, 344 F.R.D. 207, 216 (D.N.J. 2023) (permitting redactions for personal identifying information).

Finally, Plaintiffs' proposal would also bar the PBM Defendants from redacting the identities of non-PBM employee members of P&T Committees. Every other ESI Protocol to which the PBMs were parties has included a provision permitting the PBMs to redact this information. Plaintiffs can offer no reason to deviate here. Preserving the strict anonymity of the independent members of the PBMs' respective P&T Committees is vitally important. The independent members of the P&T Committees are not employees of the PBM—they are independent practicing physicians and pharmacists. The P&T Committees evaluate only the clinical effectiveness of drugs considered for inclusion on a potential formulary; cost and financial information (such as rebates) play no role in their decision. There are other formulary development committees that may consider cost and financial information for certain drugs when making formulary recommendations, and the PBMs do not seek to redact the identity of any members of those other committees. Nor do the PBMs seek to redact the identity of any PBM employees who are involved with the P&T Committees. But the PBMs consistently and aggressively strive to protect the anonymity of the independent P&T Committee members, because doing so is necessary to ensure the integrity and independence of this P&T Committee process. Absent this protection, those with an interest in formulary decision outcomes could potentially attempt to influence or retaliate against the independent P&T Committee members.

Indeed, the identity of those P&T Committee members is on such a need-to-know basis that very few individuals *within the PBMs themselves* are permitted to know this information. In short, the independent membership of the P&T Committee is one of the most guarded secrets at each PBM. There is no need to disclose their identities here: the identities of these members are not relevant to Plaintiffs' allegations about insulin pricing, and redacting that information will not affect the ability of the parties to understand any responsive documents.

To be clear, prior ESI Protocols did not contemplate, *and Defendants do not seek*, *carte blanche* approval to redact for relevance. Rather, Defendants simply ask for the same limited redaction and slipsheeting ability used (without issue) in past insulin pricing cases. *See* Ex. A, Rows 11, 12.

5. Database Production

Under prior ESI Protocols, Defendants provided information about the databases or platforms from which they produced structured data, and the parties met-and-conferred regarding the identification and format of that data. Those protocols also required the parties to meet-and-confer regarding any third-party license or software/hardware issues that may affect the receiving party's access or use of those data productions. Despite that prior system having worked without issue, Plaintiffs now seek to upend it, demanding extensive and preemptive information regarding all of Defendants' databases (data, fields, schema)—regardless of whether Plaintiffs actually propound any document requests seeking data from those databases—while also striking provisions that enable Defendants to meet their confidentiality or licensing obligations related to those databases. *See* Ex. A, Row 13. Plaintiffs' overbroad demands with respect to databases are more akin to requests for direct access to an opposing party's information systems—which the Rules and courts frown upon—rather than production specifications. *See Uddin v. O'Brien*

Rest. Holding Co., LLC, 2016 WL 11779534, at *2 (S.D.N.Y. Dec. 2, 2016) (Rule 34 "is not meant to create a routine right of direct access to a party's electronic information system"). These changes from the previously agreed provisions are disproportionately burdensome and unnecessary, and Plaintiffs have provided no reason to deviate from prior practice.

6. Color and Natives

In another deviation from well-established practice (including in prior insulin pricing cases), Plaintiffs demand that all documents be produced in color and in native format as a matter of course. See Ex. A, Row 10. The significant production costs, processing time, and hosting fees attributable to extensive color production are unnecessary. See Sedona Principles. Third Ed., 19 Sedona Conf. J at 173 ("Parties should not demand forms of production ... for which they have no practical use."); Dizdar v. State Farm Lloyds, 2015 WL 12780640, at *11 (S.D. Tex. 2015) (many documents contain color with no value (e.g., logos)). Nor do the Federal Rules require native file productions, particularly given that native ESI "may not be reasonably usable or functional to access, cull, analyze, search, and display," and "the cost and effort required to produce [ESI] in native format may not be proportional to the needs of the case." See Sedona Principles, Third Ed., 19 Sedona Conf. J. at 174–176 ("To be 'reasonably usable,' the form of ESI need not necessarily be its native format..."); Dizdar, 2015 WL 12780640, at *10-11 (declining to order native format productions where non-native format was "reasonably usable"). To strike the balance of proportionality, Defendants' proposed ESI Protocol takes the reasonable position that "[s]preadsheets, audio/visual/multimedia, and other files that are not conducive to production in image format shall be produced in Native Format." See Ex. A, Row 10. It also carves out a mechanism for receiving parties to request color files where desired, and notes that the producing party "will not unreasonably deny" the request to produce a document in

color. See Ex. A, Row 10. This process, which has been used without issue throughout discovery in the prior insulin pricing cases, is more than sufficient for Plaintiffs' needs here.

D. Plaintiffs inappropriately seek to expand discovery obligations beyond the scope of the Federal Rules.

In their latest counterproposal, Plaintiffs for the first time sought to expand the scope of the ESI Protocol to impose discovery obligations that go beyond the bounds of the Federal Rules by changing every use of the word "responsive" to "relevant or responsive." *See, e.g.*, Ex. A, Rows 4, 5, 6, 8, 11, 13. This is a distinction that matters.

Parties "may obtain discovery" of matters "relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). Rule 34, in turn, provides a mechanism for parties to request documents. *See* Fed. R. Civ. P. 34(a). But the Federal Rules do not impose an affirmative obligation on parties to produce *everything* relevant to a matter. *See* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 11.41 (2004) ("Fundamental to controlling discovery is directing it at the material issues in controversy. . . . This underlying principle of proportionality means that even in complex litigation, discovery does not require leaving no stone unturned."). Rather, parties produce documents and ESI that are "relevant *and responsive*" to requests served under Rule 34. *United States for Use & Benefit of M. Frank Higgins & Co. v. Dobco Inc.*, 2023 WL 5302371, at *4 (S.D.N.Y. Aug. 17, 2023) (emphasis added). Every ESI protocol in the insulin pricing cases to date, and Defendants' draft here, focuses on identification and production of "*responsive* ESI and documents."

Yet Plaintiffs' most recent draft repeatedly adds "relevant" with "responsive"—while also including the broadening term "potentially" before one or the other—in an attempt to broaden Defendants' discovery obligations and make Defendants do Plaintiffs' work for them.

See, e.g., Ex. A, Rows 4, 5, 6. To be clear, Defendants have complied with, and will continue to

fulfill, their obligations under the Federal Rules. But Plaintiffs' last-second change appears designed to impose an affirmative obligation on Defendants to identify and produce all potentially relevant documents in their possession *irrespective* of what Plaintiffs request during the discovery process. Plaintiffs cannot ignore the Federal Rules and turn an ESI protocol into a vague, ambiguous omnibus document request.

Plaintiffs' new ESI Protocol proposals were absent from the prior ESI Protocols for good reason. To maximize efficiency and promote fairness in this MDL, to maintain consistency with the Federal Rules and prior and ongoing insulin pricing discovery, and to allow MDL discovery to begin meaningfully, Defendants respectfully request that the Court enter Defendants' proposed ESI Protocol attached hereto as Exhibit C.

Dated: March 22, 2024 Respectfully submitted,

/s/ Liza Walsh	/s/ Patrick Harvey
Liza Walsh	Patrick Harvey
Melissa L. Patterson	Attorney for Defendant
Attorneys for Defendant	Express Scripts Defendants
Sanofi-Aventis U.S. LLC	- · · ·
/s/ Andrew Yaphe	/s/ Joshua Podoll
Andrew Yaphe Andrew Yaphe	Joshua Podoll
1	
Attorney for Defendant	Attorney for Defendant
Novo Nordisk Inc.	CVS Caremark
/s/ Ryan Moorman	/s/ Kelley Barnaby
Ryan Moorman	Kelley Barnaby
Attorney for Defendant	Attorney for Defendant
Eli Lilly	OptumRx